RADIOMETER

EC Declaration of Conformity

Radiometer Medical ApS
Åkandevej 21
DK-2700 Brønshøj
Denmark

We hereby declare that the product(s) described below meets the applicable requirements of Directive 98/79/EC of the European Parliament and of the Council of October 27, 1998, on *in vitro* diagnostic medical devices (IVDD) as specified in Annex III.

Class: ☒ General ☐ Annex II/List A ☐ Annex II/List B
☐ Self-testing ☐ Performance Evaluation

Product family: ABL90 FLEX Series, from Software version V2.3

Model Name	Article No.	Ref. No.	GMDN Code*	From Serial/ LOT No.
ABL90 FLEX Analyzer	N/A	393-090	56667	Run 27
Qualicheck Adapter	N/A	924-646	35074	N/A
Sensor Cassette SC90	N/A	946-005	30201	Run 0015
		946-008		Run 0001
		946-009		Run 0001
		946-010		Run 0001
		946-013		Run 0001
		946-051		Run 0001
		946-052		Run 0001
		946-053		Run 0001
		946-054		Run 0001
		946-055		Run 0001
		946-056		Run 0001
		946-059		Run 0001
Solution Pack SP90	N/A	944-157	35933	Run0163 AV-03
Solution Pack SP90	N/A	944-197	35933	Run 0002 AV 01
Clot Catcher	N/A	906-026	37565	N/A
ABL90 FLEX Inlet Clip	N/A	925-047	56667	N/A
ABL90 FLEX Flush Device	N/A	905-918	56667	N/A
ABL90 FLEX sBox	N/A	905-917	56667	N/A

*: According to the nomenclature provided in ISO/TS-20225

Notified Body:
As specified in the Directive and Annex mentioned above, the conformity assessment procedure for this class of product does not require the involvement of a Notified Body.

Issuance:
Name: Gitte Juel Friis
Title: RA Director
Place: Copenhagen, Denmark
Signature:
Date: 23. November 2012